DEC 0 9 2002

Special 510(k) Device Modification
PREMARKET NOTIFICATION
SAFETY AND EFFECTIVENESS SUMMARY

SurgASSIST™ Right Angle Linear Cutter
Digital Loading Unit™
30mm, 45mm, 60mm - Vascular
with Reloads

In Accordance with 21 CFR Section 807.92 Power Medical Interventions, Inc., is submitting the following Safety and Effectiveness summary.

1) Submitter Information:

Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938
267-775-8100 Ph
267-775-8123 Fax

Applicant: Barbara J. Whitman

Date of Notification: July 12, 2002

2) Name of Device:

Trade Name: SurgASSIST™
Right Angle Linear Cutter DLU
30 mm, 45 mm and 60 mm - Vascular
with Reloads

Common Name: Linear Cutter with Implantable Staples and Reloads

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

a) SurgASSIST™ Right Angle Linear Cutter Digital Loading Unit™, 30 mm, 45 mm and 60 mm with Titanium Implantable Staples and Reloads, Power Medical Interventions, Inc., New Hope, PA. REF RALC30, RALC45, RALC60, RALCR30, RALCR45, RALCR60 (K021701).

b) ETS Compact-Flex45 Articulating Endoscopic Linear Cutter, Vascular/Thin. Ethicon Endo-Surgery, Inc., Cincinnati, Ohio. REF SCW45 (K002398).

4) Device Description:

The devices described here are Right Angle Linear Cutter Digital Loading Units™(DLUs), 30 mm, 45 mm and 60 mm, Vascular, with Reloads for single patient use. All have a maximum diameter of 3.1". Both DLUs and Reloads are supplied pre-sterilized and ready for use upon removal from their packaging.

The 30 mm Vascular DLU can only be used with the 30 mm Vascular Reload.

The 45 mm Vascular DLU can only be used with the 45 mm Vascular Reload.

The 60 mm Vascular DLU can only be used with the 60 mm Vascular Reload.

The DLU contains a staple-forming anvil. The anvil acts with the staple cartridge to compress and position layers of tissue in readiness for stapling and cutting. At the same time, the anvil provides support and a means for correctly forming staples while they are closed sequentially along the tissue, followed by the cutting blade. The Right Angle Linear Cutter Vascular DLU is perpendicular to the Flex Shaft, forming an extension to the Flex Shaft, to which they are connected.

A loaded DLU is used to anastomose tubular structures by applying staples through the tissue and forming the staples to a controlled closed condition to secure the layers of tissue together. It also severs the tubular structure.

Right Angle Linear Cutter Vascular Reloads contain staples, a cutting blade, and the means to simultaneously force staples toward the anvil. The cutting blade is advanced in conjunction with the staple pushers so that tissue is simultaneously stapled and cut.

The DLUs are attached to the end of the FlexShaft (FS), which contains a pair of flexible rotary drive shafts within an overall flexible shaft. The other end of the FS is connected to the Power Console (PC), which applies mechanical power to the drive shafts. DLUs have all functions powered by the PC. The

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FS has a short steerable section at the distal end (near the attached DLU) so that the angle of attack (attitude) of the DLU can be adjusted by the surgeon to optimize patient accessibility.

The surgeon operates a DLU via a hand held electronic Remote Control Unit (RCU).

The DLUs have quick attach and release means for coupling to the FS. No tools are required. DLUs are pushed onto the FS end, snapping and locking into place. To remove a DLU from the FS, a sleeve on the DLU at the junction with the FS is rotated by hand.

DLU designs shall allow for attachment of their corresponding Reloads, but shall inhibit attachment of incompatible Reloads. Each Reload has an integral electronic memory module. This identifies the type and size of the Reload being used.

5) Indications For Use -

The SurgASSIST™ Right Angle Linear Cutter Digital Loading Unit™, 30 mm, 45 mm and 60 mm, Vascular with Reloads has applications for general and endoscopic surgery including multiple open or minimally invasive general, gynecological, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures for transection, resection, and/or creation of anastomoses. They can be used with staple line or tissue buttressing material such as bovine pericardium.

6) Comparison to Predicate Devices

The following table compares the subject Right Angle Linear Cutter DLU, 30 mm, 45 mm and 60mm, Vascular, with Reloads to the previously cleared predicate Right Angle Linear Cutter DLU (K012809) device and the Ethicon ETS Compact-Flex45 Articulating Endoscopic Linear Cutter, Vascular/Thin.

Right Angle Linear Cutter DLU Product Features Comparison Chart

Features & Description	SurgASSIST™ Right Angle Linear Cutter DLU 30mm, 45mm, 60mm – Vascular with Reloads	SurgASSIST™ Right Angle Linear Cutter DLU 30mm, 45mm, 60mm with Reloads	Predicate Ethicon ETS Compact-Flex45 Articulating Endoscopic Linear Cutter, Vascular/Thin
Name	SurgASSIST™ Right Angle Linear Cutter DLU Vascular with Reloads	SurgASSIST™ Right Angle Linear Cutter DLU with Reloads	ETS Compact-Flex45 Articulating Endoscopic Linear Cutter, Vascular/Thin
Manufacturer of Record	Power Medical Interventions, Inc.	Power Medical Interventions, Inc.	Ethicon Endo-Surgery, Inc.
Contract Manufacturer	Lacey Manufacturing Bridgeport, CT	Lacey Manufacturing Bridgeport, CT	Ethicon Endo-Surgery, Inc.
510(k) Clearance Numbers	Subject of this Notification	K021701	K002398
Product Codes	RALC30V, RALC45V, RALC60V RALCR30V, RALCR45V, RALCR60V	RALC30, RALC45, RALC60 RALCR30, RALCR45, RALCR60	SCW45 TR45W
Intended use	Has applications for general and endoscopic surgery including multiple open or minimally invasive general, gynecological, urologic (including radical prostatectomy), thoracic and pediatric surgical procedures for transection, resection, and/or creation of anastomoses. They can be used with staple line or tissue buttressing material such as bovine pericardium.	Has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.	Application in gastroenterology for transection, resection, and/or creation of anastomoses and can be used in multiple open or minimally invasive surgical procedures, including radical prostatectomy, and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

Right Angle Linear Cutter DLU Product Features Comparison Chart

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Features & Description	SurgASSIST™ Right Angle Linear Cutter DLU 30 mm, 45 mm, 60 mm – Vascular with Reloads	SurgASSIST™ Right Angle Linear Cutter DLU with Reloads – 30 mm, 45 mm, 60 mm	Predicate Ethicon ETS Compact-Flex45 Articulating Endoscopic Linear Cutter, Vascular/Thin
FDA Class (System)	II	II	II
Physical Characteristics			
Number of Staples	30mm Vascular- 46 staples 45mm Vascular - 69 staples 60mm Vascular - 92 staples	30mm - 22 staples 45mm - 32 staples 60mm - 46 staples	66
Rows of Staples	30mm Vascular -6 rows 45mm Vascular - 6 rows 60mm Vascular - 6 rows	30mm - 4 rows 45mm - 4 rows 60mm - 4 rows	6 rows
Staple Crown Dimension	30mm Vascular – 2.4 mm 45mm Vascular – 2.4 mm 60mm Vascular – 2.4 mm	30mm – 4.0 mm 45mm – 4.0 mm 60mm – 4.0 mm	2.7 mm
Staple Leg Dimension	30mm Vascular – 2.3 mm 45mm Vascular - 2.3 mm 60mm Vascular – 2.3 mm	30mm - 4.4 mm 45mm - 4.4 mm 60mm - 4.4 mm	2.5 mm
Staple Thickness	30mm Vascular - 0.20 mm 45mm Vascular - 0.20 mm 60mm Vascular - 0.20 mm	30mm - 0.23mm 45mm - 0.23mm 60mm - 0.23mm	0.20 mm
Staple Closed Range	30mm Vascular – 1.0 mm 45mm Vascular - 1.0 mm 60mm Vascular – 1.0 mm	30mm - 1.2 / 2.0mm 45mm - 1.2 / 2.0mm 60mm - 1.2 / 2.0mm	1.0 mm
DLU Internal Power	None	None	None
Digital Information	Memory module containing digital data for identification, etc.	Memory module containing digital data for identification, etc.	None
How Supplied	Sterile - Single Patient Use	Sterile - Single Patient Use	Sterile - Single Patient Use

Right Angle Linear Cutter DLU Product Features Comparison Chart

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Features & Description	SurgASSIST™ Right Angle Linear Cutter DLU 30 mm, 45 mm, 60 mm – Vascular with Reloads	SurgASSIST™ Right Angle Linear Cutter DLU with Reloads 30 mm, 45 mm, 60 mm	Predicate Ethicon ETS Compact-Flex45 Articulating Endoscopic Linear Cutter, Vascular/Thin
Method of Sterilization	Ethylene Oxide Gas (ETO)	Ethylene Oxide Gas (ETO)	Irradiation
Packaging			
Digital Loading Unit™	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid
Reloads	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 9 2002

Power Medical Interventions, Inc.
Barbara J. Whitman
Regulatory Affairs Manager
110 Union Square Drive
New Hope, Pennsylvania 18938-1364

Re: K022313
Trade/Device Name: SurgASSIST™ Right Angle Linear Cutter DLU™ 30mm, 45mm & 60mm- Vascular with Reloads
Regulation Number: 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 30, 2002
Received: October 31, 2002

Dear Ms. Whitman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) No. K022313

Device Name: *SurgASSIST™*
Right Angle Linear Cutter
Digital Loading Unit™
30mm, 45mm, 60mm - Vascular
with Reloads

INDICATIONS FOR USE:

The SurgASSIST™ Right Angle Linear Cutter Digital Loading Unit™, 30 mm, 45 mm and 60 mm, Vascular with Reloads has applications for general and endoscopic surgery including multiple open or minimally invasive general, gynecological, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures for transection, resection, and/or creation of anastomoses. They can be used with staple line or tissue buttressing material such as bovine pericardium.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ✓ OR Over-The-Counter Use _____
Per 21CFR §801.109

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K022313

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